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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/497,891	02/04/2000	Hermann Kuenzer	SCH-1692	8032

7590 12/18/2001

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[REDACTED] EXAMINER

QAZI, SABIHA NAIM

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 12/18/2001

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.  
09/497,891

Applicant(s),

Kuenzer H. et al.

Examiner

Sabiha Qazi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on Oct 5, 2001

2a)  This action is FINAL.      2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4)  Claim(s) 1-52 is/are pending in the application.

4a) Of the above, claim(s) 26-51 is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-25 and 52 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some\* c) None of:

1.  Certified copies of the priority documents have been received.

2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

15)  Notice of References Cited (PTO-892)

18)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

16)  Notice of Draftsperson's Patent Drawing Review (PTO-948)

19)  Notice of Informal Patent Application (PTO-152)

17)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

20)  Other: \_\_\_\_\_

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**First Office Actions on Merits**

**Status of the Application**

Claims 1-52 are pending.

No claim is allowed.

Claims 1-25 and 52 are examined to the extent of elected invention when double bonds are absent.

Others are withdrawn from consideration as non elected invention. Response and election with traverse filed in paper no. 9 is hereby acknowledged. The traversal is on the grounds that the restriction was based on misinterpretation of claims, because double bonds in rings B, C and/or D are optional. This is incorrect, because restriction was done by carefully looking at claims and considering optional double bonds. A reference cannot be applied to reject the invention if the bonds are at different rings. Each represents a separate invention and can be entitled for a separate patents. The restriction is considered proper for the same reasons set forth in our previous actions.

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

2. Claims rejected under 35 U.S.C. 102(b) as being anticipated by Siebert et al. (DN 110:75884, HCAPLUS, abstract of DD 253249). See compound of RN 19882-03-2 (HCAPLUS) which has 16, 17 hydroxy group, and at 18-position an ethyl group which is claimed in the instant invention. See abstract.

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3. Claims rejected under 35 U.S.C. 102(b) as being anticipated by Anner, George et al. (DN 79:137384, HCAPLUS, abstract of CH 538460). Anner et al discloses structurally similar highly active estradiol which embraces Applicant's claimed invention. See compound of RN 28834-40-4 where 16 and 17 position are hydroxy groups at 7 and 18-position a methyl group is present.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims are rejected under 35 U.S.C. 103(a) as being unpatentable over Siebert et al. (DN 110:75884, HCAPLUS, abstract of DD 253249). Siebert teaches procedure for preparing 16 alpha, 17 beta diols, useful as estrogens which embraces applicant's claimed compounds. See compound of RN 19882-03-2 (HCAPLUS) which has 16, 17 hydroxy group, and at 18-position an ethyl group which is claimed in the instant invention. See the abstract.

2. Claims are rejected under 35 U.S.C. 103(a) as being unpatentable over Anner, George et al. (DN 79:137384, HCAPLUS, abstract of CH 538460). Anner et al. discloses structurally similar highly active estradiol which embraces Applicant's claimed invention. See compound of RN 28834-40-4 where 16 and 17 position are hydroxy groups at 7 and 18-position a methyl group is present. All the substituents are instantly claimed. These compounds posses estrogenic activity and inhibited ovulation and embryo

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implantation. See the abstract. The claims differ from the reference by claiming a broader genus than the references cited above. However, the compounds as instantly claimed are taught by the prior art of record.

It would have been obvious to one skilled in the art at the time of invention to prepare addition beneficial compounds as estrogens because structurally similar compounds are taught by the prior art supra as estrogens. For example prior art teaches ethyl or a methyl groups at 18-position. In instant claims ethyl, methyl, trifluoromethyl or pentafluoroethyl groups are claimed. As is clear instant claims are broader at every position than the prior arts. The motivation is in the substituents taught by the prior art.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a). Elected species is allowable.

#### **Telephonic Inquiry**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha N. Qazi, whose telephone number is (703) 305-3910. The examiner can normally be reached on Monday through Friday from 8 a.m. to 6 p.m. The fax phone number for this Group is (703) 308-4556. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.



Sabiha N. Qazi, Ph.D.

12/12/01

Primary Examiner,

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